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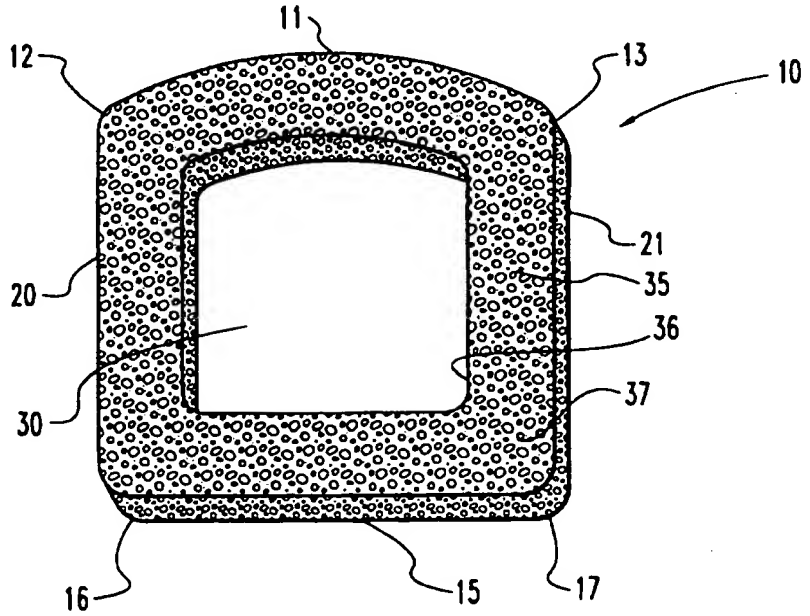
(54) Title: INTERVERTEBRAL SPACER

(57) Abstract

One embodiment of a spinal spacer (10) includes an anterior wall (11) having a convexly curved anterior surface and opposite ends (12, 13), a posterior wall (15) having opposite ends (16, 17), two lateral walls (20, 21), each integrally connected between the opposite ends (12, 13, 16, 17) of the anterior (11) and posterior (15) walls to define a chamber (30). The walls (11, 15, 20, 21) include a superior face (35) and an inferior face (38), each defining friction or vertebral engaging surfaces. In one specific embodiment, a solid D-shaped spacer (40) is provided. In another specific embodiment, the spacer (10, 40) is composed of a biocompatible bone ingrowth material that has a sufficient surface roughness to provide a friction fit. In a still another embodiment, the bone ingrowth material includes a plurality of continuous interconnected pores that contain a bone morphogenic protein to facilitate bone ingrowth into the spacer.



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INTERVERTEBRAL SPACER

This application is a continuation-in-part of application serial no. 08/543,563, filed on October 16, 1995.

FIELD OF THE INVENTION

The present invention broadly concerns devices for stabilizing the spine and devices for implantation between vertebrae, and more particularly in the intradiscal space. Specifically, the invention concerns hollow spacers which include a porous bone ingrowth material.

BACKGROUND OF THE INVENTION

Intervertebral discs, located between the endplates of adjacent vertebrae, stabilize the spine, distribute forces between vertebrae and cushion vertebral bodies. A normal intervertebral disc includes a semi-gelatinous component, the nucleus pulposus, which is surrounded and confined by an outer, fibrous ring called the annulus fibrosis. In a healthy, undamaged spine, the annulus fibrosis prevents the nucleus pulposus from protruding outside the disc space.

Spinal discs may be displaced or damaged due to trauma, disease or aging. Disruption of the annulus fibrosis allows the nucleus pulposus to protrude into the vertebral canal, a condition commonly referred to as a herniated or ruptured disc. The extruded nucleus pulposus may press on the spinal nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs may

also deteriorate due to the normal aging process or disease. As a disc dehydrates and hardens, the disc space height will be reduced leading to instability of the spine, decreased mobility and pain.

Sometimes the only relief from the symptoms of these conditions is a discectomy, or surgical removal of a portion or all of an intervertebral disc followed by fusion of the adjacent vertebrae. The removal of the damaged or unhealthy disc will allow the disc space to collapse. Collapse of the disc space can cause instability of the spine, abnormal joint mechanics, premature development of arthritis or nerve damage, in addition to severe pain.

Bone grafts are often used to fill the intervertebral space to prevent disc space collapse and promote fusion of the adjacent vertebrae across the disc space. For example, in the Smith-Robinson technique for cervical fusion, the surgeon prepares the endplates of the adjacent vertebral bodies to accept a graft after the disc has been removed. The endplates are generally prepared to be parallel surfaces with a high speed burr. The surgeon sculpts the graft to fit tightly between the bone surfaces so that the graft is held by compression between the vertebral bodies. The bone graft is intended to provide structural support and promote bone ingrowth to achieve a solid fusion of the affected joint.

Unfortunately, the use of bone grafts presents several disadvantages. Autografts, bone material surgically removed from the patient, can be undesirable because they may not yield a sufficient quantity of graft material. The additional surgery to extract the autograft also increases the risk of infection and blood loss. The structural integrity at the donor site can be reduced. Furthermore,

some patients complain that the graft harvesting surgery is more painful than the fusion surgery.

Allograft material, which is obtained from donors of the same species, is more readily obtained. However, allografts can be disadvantageous because of disease transmission, immune reactions and religious objections. Furthermore, allogenic bone does not have the osteoinductive potential of autogenous bone and therefore may provide only temporary support.

Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Slippage of the graft may cause neural and vascular injury, as well as collapse of the disc space.

Prosthetic implants can be used to prevent collapse of the disc space. The implant must provide temporary support and allow bone ingrowth. Success of the discectomy and fusion procedure requires the development of a contiguous growth of bone to create a solid mass because the implant may not withstand the compressive loads on the spine for the life of the patient.

Many attempts to restore the intervertebral disc space after removal of the disc have relied on metal devices.

U.S. Patent No. 4,878,915 to Brantigan teaches a solid metal plug. U.S. Patent Nos. 5,044,104; 5,026,373 and 4,961,740 to Ray; 5,015,247 to Michelson and U.S. Patent No. 4,820,305 to Harms et al., U.S. Patent No. 5,147,402 to Bohler et al. and 5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, there are several disadvantages associated with the use of these metal implants. For example, metal implants may stress shield the bone graft, increasing the time required for fusion to occur.

Most of the prior implants do not adequately address the need for obtaining a solid fusion. Solid body metal implants do not allow bone ingrowth which may lead to the eventual failure of the implant. Surface porosity in such solid implants may not correct this problem because it often will not allow sufficient ingrowth to provide a solid bone mass strong enough to withstand the loads of the spine. On the other hand, the hollow cage structures of Harms, Ray, Michelson, Bohler and Brantigen allow ingrowth. These devices can also be filled with bone graft material to promote bone growth needed for solid fusion. However, the large openings disclosed in these references, while allowing bone ingrowth, reduce the amount of metal providing structural support, which can limit the implant's load bearing capability until fusion occurs.

Unfortunately, many of these metal devices are also difficult to machine and therefore expensive. For example, the superior and inferior surfaces of Brantigan (U.S. Patent No. 5,192,327) define ridges for interdigitation with adjacent implants for stacking and biting into the endplates of adjoining vertebrae. Bohler (U.S. Patent No. 5,147,402) discloses that the surface of the implant can be roughened to promote fusion. These features require more expensive machining and may also compromise the strength of the

implant. Moreover the structure of these types of implants do not readily lend themselves for manufacture in smaller sizes for use in the cervical spine.

A need has remained for fusion devices which encourage and support bone ingrowth and avoid stress shielding yet provide sufficient strength and resistance to expulsion to support the vertebral column until the adjacent vertebrae are fused. A need has also remained for devices which are efficiently and inexpensively manufactured and which avoid the need for trial and error trimming of graft material to fit the intradiscal space.

SUMMARY OF THE INVENTION

In accordance with the invention, spinal spacers are provided for engagement between vertebrae. The spacers are sized and configured to fill a space between adjacent vertebrae and include an anterior wall having opposite ends, a posterior wall having opposite ends, and two lateral walls. In one embodiment, the lateral walls are each connected between the opposite ends of the anterior and posterior walls to define a chamber. The walls also define a superior face having a first opening which is in communication with the chamber and an opposite inferior face having a second opening which is also in communication with the chamber. The superior and inferior faces each define friction or vertebral engaging surfaces. In one specific embodiment, the spacer is D-shaped having a convexly curved anterior surface on the anterior wall. In another embodiment, a solid D-shaped spacer is provided. In another specific embodiment, the implant has a basic flat geometry without any machined ridges or teeth. The smooth-shaped spacer provides a friction fit by virtue of a biocompatible bone ingrowth material having interconnected continuous pores. The invention also contemplates an interbody fusion device having a height approximating the height of a human disc space.

One object of the invention is to provide an implant for engagement between vertebrae which encourages bone ingrowth and resists expulsion of the implant. Another object of the invention is to provide an implant which restores the intervertebral disc space and supports the vertebral column while promoting bone ingrowth without stress shielding.

A further object is to provide a vertebral body replacement device for use in restoring the space left by

the removal of a defective spinal element while promoting fusion between the adjoining healthy vertebral bodies. Another object of the present invention is to provide spinal spacers which can be efficiently and inexpensively manufactured and which avoid the need for trial and error trimming of graft material to fit the intradiscal space.

One benefit of the implants of the present invention is that they provide a stable scaffold for bone ingrowth before fusion occurs. An additional benefit is that the invention provides structure for the space resulting from the removal of an intervertebral disc without internal fixation. This invention promotes bone ingrowth without the need for invasive autograft harvesting or the risks and limitations associated with allograft. Other objects and further benefits of the present invention will become apparent to persons of ordinary skill in the art from the following written description and accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top perspective view of the spinal implant according to one embodiment of this invention.

FIG. 2 is a top perspective view of an implant of this invention.

FIG. 3 is a front elevational view of the anterior end of the spacer depicted in FIG. 2.

FIG. 4 is a top perspective view of a solid spacer of this invention.

FIG. 5 is a top elevational view of the spacer shown in FIG. 4.

FIG. 6 is an end elevational view of the posterior end of the spacer shown in FIG. 4.

FIG. 7 is a top perspective view of a spinal implant having an osteogenic material packed within the chamber according to one embodiment of this invention.

FIG. 8 depicts a tool which may be used to implant the spacers of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention provides spinal spacers for engagement between vertebrae. Spacers of this invention are made of a preferred biocompatible bone ingrowth material having interconnected continuous pores that provide a structure for bone ingrowth which resembles the natural porosity of bone. This material allows manufacture of smooth-shaped spacers which provide a friction fit with the adjacent vertebrae by virtue of the inherent properties of the material. This friction fit resists expulsion of the implant and may eliminate the need for internal fixation. The inventive implants restore the intervertebral disc space, provide a large surface area for bone growth and eliminate the need for invasive autograft harvesting and trial and error trimming of graft material to fit the intradiscal spaces. Implants according to this invention provide immediate load bearing capability and support for the vertebral column without stress shielding the bone implant material.

A spacer 10 for engagement between the vertebrae in accordance with a preferred embodiment of the present

invention is depicted in FIGS. 1-3. The spacer 10 includes an anterior wall 11 having opposite ends 12, 13, a posterior wall 15 having opposite ends 16, 17 and two lateral walls 20, 21. Each of the lateral walls 20, 21 is connected between the opposite ends 12, 13, 16, 17 of the anterior 11 and posterior 15 walls to define a chamber 30. The walls also include the superior face 35 which defines a first opening 36 in communication with the chamber 30. The superior face 35 includes a first friction or vertebral engaging surface 37. As shown in FIG. 3, the walls further include an opposite inferior face 38 defining a second opening 39 which is in communication with the chamber 30. The chamber 30 is preferably sized to receive osteogenic material to facilitate bone growth. The inferior face 38 includes a second friction or second vertebral engaging surface (not shown) which is similar to or identical to the first friction or vertebral engaging surface 37.

In one specific embodiment for an intervertebral disc replacement implant, a hollow D-shaped spinal spacer is provided. The anterior wall 11 as shown in FIGS. 1-3 is convexly curved. This anterior curvature is preferred to conform to the geometry of the adjacent vertebral bone and specifically to the harder cortical bone of the vertebrae. The D-shape of the spacer 10 also prevents projection of the anterior wall 11 outside the anterior aspect of the disc space, which can be particularly important for spacers implanted in the cervical spine.

Another embodiment in accordance with the principles of this invention is depicted in FIGS. 4-6. In this embodiment for a spinal prosthesis for engagement between vertebrae, a spacer 40 is provided which includes a spacer body 41 composed of a biocompatible bone ingrowth material having interconnected, continuous pores. The body 41 includes an

anterior face 42 and a posterior face 43 which is spaced apart from and opposing the anterior face 42. The body 41 also includes two spaced apart and opposing lateral faces 44. A superior face 45 defining a first vertebral engaging surface 46 is spaced apart from and opposing an inferior face 47. The inferior face 47 defines a second vertebral engaging surface (not shown).

Preferably, the anterior face 42 of the spacer 41 is convexly curved and the posterior face 43 is flat to form a solid D-shape block. The solid block embodiment 40 provides more surface area for bone ingrowth and more load bearing area than the spacers 10 that include a chamber 30. The ingrowth material of the body 41 eliminates some of the concerns normally associated with a solid metal spacer such as stress shielding and pseudoarthrosis. The interconnected, continuous pores provide a scaffold for contiguous bone growth. This characteristic enables a solid body design without compromising the success of the fusion.

The spacers 10, 40 of this invention are preferably shaped to be conveniently incorporated into current surgical techniques. For example, a flat posterior wall 15 or face 43, as shown in FIGS. 4-6, can be easily incorporated into Smith Robinson surgical fusion technique. See, for example, Smith, M.D., G.W. and R.A. Robinson, M.D., "The Treatment of Certain Cervical-Spine Disorders By Anterior Removal Of The Intervertebral Disc And Interbody Fusion", J. Bone And Joint Surgery, 40-A:607-624 (1958) and Cloward, M.D., R.B., "The Anterior Approach For Removal Of Ruptured Cervical Disks", in meeting of the Harvey Cushing Society, Washington, D.C., April 22, 1958. After partial or total discectomy and distraction of the vertebral space, the surgeon prepares the end plates for the spacer 10, 40 preferably to create flat posterior and lateral edges. The spacer 10, 40 fits snugly

with its flat surfaces against the posterior and lateral edges which prevents medial and lateral motion of the spacer 10, 40 into vertebral arteries and nerves. This also advantageously reduces the time required for the surgery by eliminating the trial and error approach to achieving a good fit with bone grafts. Normally, the surgeon is required to repeatedly whittle away the graft to obtain the correct size to fit in the intervertebral space.

Advantageously, the intervertebral spacers of the present invention may not require internal fixation. The spacers are contained by the compressive forces of the surrounding ligaments and muscles, and the disc annulus if it has not been completely removed. Temporary external immobilization and support of the instrumented and adjacent vertebral levels is generally recommended until adequate fusion is achieved. For example, a cervical collar is recommended when the spacer is implanted in the cervical spine.

The spacers 10, 40 of this invention are preferably composed of a biocompatible bone ingrowth material having interconnected continuous pores throughout the body of the spacer. Any suitable material is contemplated which has a compressive endurance (at five million cycles) of at least 100 pounds and a compressive strength of at least about 350 pounds. Most preferably the bone ingrowth material is a biocompatible composite which includes a non-metallic rigid foam substrate formed by an interconnected network of carbonaceous material defining continuous, interconnected pores and a metallic film substantially covering the interconnected network. Such materials are described in U.S. Patent No. 5,282,861 to Kaplan which is herein incorporated by reference. The metallic film preferably includes a Group VB transition metal such as tantalum,

niobium or alloys thereof. Tantalum is most preferred because it is thought to be the most biocompatible, corrosion resistant metal for providing structure. Most preferably, the rigid foam substrate is carbon and the metallic material is tantalum which is deposited onto the carbon foam substrate with chemical vapor infiltration as described in Kaplan. This material is available from Implex Corp., 80 Commerce Drive, Allendale, NJ 07401-1600 and is marketed under the name Hedrocel®.

The spacers of this invention can be manufactured according to the methods described in the Kaplan 5,282,861 Patent. Alternatively, spacers can be machined from composite blocks obtained from Implex Corp., and then preferably resealed. Resealing refers to the process whereby metal is redeposited onto the carbonaceous foam material that became exposed by the machining process. Any suitable machining method which will not smear the pores of the material, such as hot wire EDM, is contemplated.

Kaplan type materials provide three important advantages: complete porosity, roughness and strength. As discussed in the Kaplan patent, the open cell tantalum material provides highly interconnected three-dimensional porosity that encourages bone ingrowth. Kaplan type materials facilitate bone ingrowth throughout the entire device for complete fusion and have the strength of metal without the disadvantages of metal such as stress shielding and incomplete fusion. Because the material of the spacers 10, 40 itself is porous and supports bone ingrowth, there is no need for extra machining of open side slots. An additional benefit of the porosity of these materials is that a bone growth inducing composition can be introduced into the pores. For example, in one embodiment, the composition includes a bone morphogenic protein in a liquid

carrier which can be injected into the pores to promote fusion. These materials also provide an unexpected benefit in that the roughness of the surface provides a friction fit between the vertebral bodies. Inherent properties of the tantalum foam material provide stability which other prior devices obtain through extra machining of teeth and ridges. The roughness features which must be machined into these prior devices may also compromise strength. Advantageously, the preferred material allows spacers of the present invention to be manufactured with a flat geometry with or without an open chamber 30.

Spacers according to this invention which are composed of a tantalum foam composite are less likely to slip than bone graft or smooth design implants due to the roughness properties of the material. Spacers 10, 40 which incorporate the tantalum open cell structure or similar biomaterials preferably have a surface roughness of at least 1 micron RMS and preferably at least about 2 microns RMS. The spacers 10, 40 may also preferably have a surface roughness of about 10 microns RMS. It has been found that these surface roughness values are sufficient to resist expulsion of the spacers under normal spinal loads.

Any biocompatible material which is highly porous and can withstand high spinal loads is contemplated. Most preferably, the biocompatible material will have surface roughness or friction properties similar to the tantalum foam material described above. The preferred material is preferably about 75-85 percent porous. The pores are defined by struts or structural members which preferably range from about 50 to about 150 microns in diameters. The thickness of the struts depends on relative porosity. The preferred material of the present invention defines at least about 10-20 pores per inch (ppi) preferably 60-65 ppi and

most preferably 80 ppi. Strength tests have shown that 80 ppi is stronger than material with lower ppi values because more tantalum foam matrix is provided. The strength of lower porosity materials can be increased by increasing the thickness of the metallic film. For cervical spacers, the relative density of the material is preferably between about 10% to about 30%. Most preferably the relative density is between about 16 to about 25%. The relative density for lumbar applications may be higher. The material is manufactured to have a mean pore size which is conducive to bone ingrowth, preferably between about 200 microns to about 850 microns and most preferably a mean pore size of about 400 or 520 microns. The pore size of 60 ppi is about 850 microns. The pore size of 80 ppi is about 520 microns. It is understood that pore size and porosity is controlled in the manufacturing process.

During a surgical implantation procedure, the surgeon may apply an osteogenic material to the device by packing the chamber 30 with an osteogenic material 48 as shown in Figure 7 or by introducing an osteogenic composition to the pores of the bone ingrowth material. Any suitable osteogenic material or composition is contemplated. For example, the osteogenic material may include osteoconductive materials such as allograft or certain bioceramics. Allograft materials may include morcellized bone graft from a bone bank. The osteogenic material preferably is an osteoinductive material such as autograft, certain bioceramics or osteoinductive proteins. Autograft may be taken from the iliac crest or may include osteocytes or other bone reamed away by the surgeon while preparing the end plates for the spacer. Bioceramics may include biphasic calcium phosphate ceramics such as hydroxyapatite/tricalcium phosphate ceramics which are well known in the art. The osteogenic compositions may comprise a therapeutically

effective amount of a bone inductive factor such as a bone morphogenic protein in a pharmaceutically acceptable carrier.

Advantageously, where graft is chosen as the osteogenic material, only a very small amount of bone material is needed to pack the chamber 30. The graft itself is not required to provide structural support as this is provided by the spacer 10. Instead the graft is merely required for its osteoconductive and/or osteoinductive properties to promote fusion across the disc space. The donor surgery for such a small amount of bone is less invasive and better tolerated by the patient. There is usually little need for muscle dissection in obtaining such small amounts of bone. The present invention therefore eliminates many of the disadvantages of autograft.

For the osteogenic compositions, any suitable carrier which provides a vehicle for introducing the osteogenic material into the pores of the bone ingrowth material or the chamber 30 of the spacer 10 is contemplated. Such carriers are well known and commercially available. One preferred carrier is an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat® Absorbable Collagen Hemostatic Agent. Another preferred carrier is an open cell polylactic acid polymer (OPLA). Other potential matrices for the compositions may be biodegradable and chemically defined calcium sulfate, tricalcium phosphate (TCP), hydroxyapatite (HA), biphasic TCP/HA ceramic, polylactic acids and polyanhydrides. Other potential materials are biodegradable and biologically well defined, such as bone or dermal collagen. Further matrices are comprised of pure proteins or extracellular matrix components. The osteoinductive material may also be an admixture of the osteoinductive cytokine and a polymeric

acrylic ester carrier. The polymeric acrylic ester can be polymethylmethacrylic. The carriers are preferably provided in strips or sheets which may be folded to conform to the chamber 30.

The choice of carrier is based on biocompatibility, biodegradability, mechanical properties and interface properties. The particular application of the compositions of the invention will define the appropriate formulation. The carrier may be any suitable carrier capable of delivering the proteins to the spacer.

Bone morphogenic proteins (BMPs) have been found to significantly decrease the time required to achieve fusion across an instrumented disc space. BMPs may be isolated and purified from bone or genetically engineered BMPs. Most preferably, the bone morphogenic protein is a BMP-2, such as recombinant human BMP-2. However, any bone morphogenic protein is contemplated including but not limited to bone morphogenetic proteins designated as BMP-1 through BMP-13. Such BMPs are available from Genetics Institute, Inc., of Cambridge, Massachusetts, and may also be prepared by one skilled in the art as described in U.S. Patent Nos. 5,187,076 to Wozney et al.; 5,366,875 to Wozney et al.; 4,877,864 to Wang et al.; 5,108,922 to Wang et al.; 5,116,738 to Wang et al.; 5,013,649 to Wang et al.; 5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al which are hereby incorporated by reference.

The BMP may be provided in freeze-dried form and reconstituted in sterile water or another suitable carrier. The carrier may be any suitable medium capable of delivering the proteins to the implant. Preferably the medium is

supplemented with a buffer solution as is known in the art. In one specific embodiment of the invention, BMP-2 is suspended or admixed in a liquid carrier, such as water or liquid collagen. The liquid can be dripped onto the spacers 10, 40 or the spacers can be immersed in a suitable quantity of the liquid, in either case for a period of time sufficient to allow the liquid to invade all of the interconnected pores throughout the spacer body.

In some cases, prior to introduction of the BMP, a BMP bonding agent is applied to the porous spacer 10, 40 so that the agent can coat the surface of the pores in the spacer body. Preferably, the agent is a calcium phosphate composition. It has been discovered that the rate of delivery of bone morphogenic proteins to the fusion site can be controlled by the use of such agents. The calcium phosphate compositions are thought to bond with the bone morphogenic protein and prevent the BMP from prematurely dissipating from the device before fusion can occur. It is further believed that retention of the BMP by the agent permits the BMP to leach out of the device at a rate that is conducive to complete and rapid bone formation and ultimately, fusion across the disc space. Any suitable, biocompatible calcium phosphate composition is contemplated. In a preferred embodiment, a layer of hydroxyapatite several microns thick is applied to the Kaplan material. The hydroxyapatite covers the tantalum film-covered ligaments while leaving the pores open. Also contemplated are tricalcium phosphate ceramics and hydroxyapatite/tricalcium phosphate ceramics.

The calcium phosphate composition may be applied to the porous biocompatible material of the implant in any suitable manner such as plasma spraying and chemical dipping where the porous material is dipped into a slurry of calcium

phosphate composition. Methods for applying a coating of calcium phosphate compositions are described in the following: U.S. Patent No. 5,164,187 to Constantz et al., U.S. Patent No. 5,1656,058 to Wang et al., U.S. Patent No. 5,030,474 to Saita et al, U.S. Patent No. 5,318,898 to Israel, U.S. Patent No. 5,330,826 to Taylor et al, U.S. Patent NO. 5,128,169 to Saita et al, Re. 34,037 to Inoue et al, U.S. Patent No. 5,068,122 to Kokubo et al, and U.S. Patent Nos. 5,188,670 and 5,279,831 to Constantz which are hereby incorporated by reference.

The present invention further contemplates an inserter 50 as depicted in FIG. 8 for facilitating the implantation of the spacers 10, 40. The inserter 50 includes a handle 51 with knurlings or other suitable patterns to enhance manual gripping of the handle. A shaft 52 extends from the handle 51 and is generally divided into two portions: a solid portion 53 and a split jaw portion 54. The split jaw portion 54 is at the distal end of the shaft 52 opposite the handle 51. In the preferred embodiment, the split jaw portion 54 includes two jaws 56 each having an offset gripping surface 58 at their free ends. As depicted in FIG. 8 the split jaw portions 54 are movable from a fully opened position as represented by the fully separated position of the gripping surfaces 58. The split jaw portion 54 is closeable to a fully closed position in which the two jaws 56 are contacting. In the fully closed position, the gripping surfaces, identified as 58' in FIG. 8, are separated by a distance sufficiently close to grip a hollow spacer 10 therebetween. In particular, the closed gripping surfaces 58' contact the side surfaces of the two lateral walls 20, 21 of the spacer 10. In one preferred embodiment, the gripping surfaces 58 are roughened or knurled to enhance the grip on the spacers 10, 40.

The inserter 50 further includes a sleeve 60 that is concentrically disposed around shaft 52. Preferably the sleeve 60 defines an inner bore 61 with a first portion 62 having a diameter slightly greater than the diameter of shaft 52. The internal bore 61 includes a flared portion 63 at its distal end 64. In the preferred embodiment, when the jaws 56 of the split jaw portion 54 are in their fully opened position, the jaws contact the flared portion 63 of the bore 61.

In the use of the inserter 50, the sleeve 60 is slid along the shaft 52, and more particularly along the opened jaws 56, to push the jaws together. As the jaws are pushed together, the gripping surfaces 58 engage and firmly grip a spacer 10, 40 as described above. This inserter can then be extended percutaneously into the surgical site to implant a spacer 10, 40 in the intradiscal space. Once the spacer is properly positioned, the sleeve 60 can be moved back toward the handle 51, so that the natural resilience of the two jaws 56 cause them to spread apart, thereby releasing the spacer 10, 40. The inserter 50 can then be withdrawn from the surgical site with the jaws fully opened, or the sleeve can be advanced along the shaft once the gripping surfaces 58 have cleared the spacer 10, 40.

Spacers according to the present invention have compressive endurance and strengths sufficient to withstand the normal loads of the spinal column. Spacers of the present invention preferably have a compressive endurance of at least 100 pounds out to 5 million cycles. Most preferably spacers of the present invention have a compressive endurance of about 500 pounds. Spacers of the present invention also preferably have compressive strengths which are greater than reported bone graft values of between

175 and 1,140 pounds. Spacers of the present invention preferably have compressive strengths of at least 350 pounds, and most preferably about 1,500 pounds.

Any suitably sized spacer is contemplated. In one specific embodiment an interbody fusion spacer according to this invention is contemplated. Preferably, the spacers 10, 40 have a height h (FIG. 3) approximating the height of a particular human disc space, such as the cervical spine. In some applications, it may be preferable that the height of the spacer 10, 40 be slightly larger than the height of a human disc space to preserve disc space height under the compressive forces of the spine and to avoid the effects of bone erosion. In one specific embodiment, a cervical spacer has a height of about 7mm, a width of about 14mm and a length (anterior to posterior) of about 14mm. In another specific embodiment, the spacer has a width and length of about 11mm and a height of between 7 and 14 mm. The invention contemplates that the walls of the spacer will be of sufficient thickness to provide structural support. In one specific embodiment for use in a cervical spine, the walls are each about 2mm thick. Appropriately sized thoracic and lumbar spacers are also contemplated to be used with appropriate surgical techniques.

Implants according to this invention combine the advantages of porous biocompatible materials with stronger materials such as metals. The implants provide immediate load bearing capability without stress shielding. The porous biocompatible material provides a large surface area for bone ingrowth and eliminates the need for invasive autograft. Devices of this invention reduce surgical time by avoiding the need for trial and error trimming of graft material to fit the intradiscal space. The biocompatible material also preferably has a surface roughness that

provides sufficient frictional properties to hold the spacer in place and avoid its ejection from the disc space. Spacers of the present invention can be efficiently and inexpensively manufactured.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A hollow spinal spacer for engagement between vertebrae, comprising:

an anterior wall having a convexly curved anterior surface and opposite ends;

a posterior wall having a flat posterior surface and opposite ends;

two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber;

said walls further defining;

a superior face defining a first opening, said opening in communication with said chamber, said superior face having a first vertebral engaging surface; and

an opposite inferior face defining a second opening, said second opening in communication with said chamber, said inferior face having a second vertebral engaging surface; and

said walls and said vertebral engaging surfaces composed of a biocompatible composite including a nonmetallic rigid foam substrate formed by an interconnected network of carbonaceous material defining continuous, interconnected pores and a tantalum film substantially covering said interconnected network.

2. The spacer of claim 1 wherein said composite at said vertebral engaging surfaces has a surface roughness of at least 1 micron root mean square.

3. The spacer of claim 2 wherein said composite at said vertebral engaging surfaces has a surface roughness of at least 2 micron root mean square.

4. A hollow spinal spacer for engagement between vertebrae, comprising:

an anterior wall having opposite ends;

a posterior wall having opposite ends;

two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to form a chamber;

said walls further defining;

a superior face defining a first opening, said opening in communication with said chamber, said superior face having a first vertebral engaging surface that is substantially flat; and

an opposite inferior face defining a second opening, said second opening in communication with said chamber, said inferior face having a second vertebral engaging surface that is substantially flat; and

said walls including a biocompatible bone ingrowth material having interconnected continuous pores.

5. The spacer of claim 4 wherein said anterior wall has a convexly curved anterior surface.

6. The spacer of claim 4 wherein said biocompatible bone ingrowth material at said vertebral engaging surfaces has a surface roughness of at least about 2 microns root mean square.

7. A hollow spinal spacer for engagement between vertebrae, comprising:

an anterior wall having opposite ends;

a posterior wall having opposite ends;

two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to

define a chamber;

said walls further defining;

a superior face defining a first opening, said opening in communication with said chamber, said superior face having a first friction surface; and

an opposite inferior face defining a second opening, said second opening in communication with said chamber, said inferior face having a second friction surface; and

said walls and said first and second friction surfaces including a biocompatible bone ingrowth material having interconnected continuous pores and a surface roughness of at least about 2 micron root mean square.

8. The spacer of claim 7 wherein said anterior wall has a convexly curved anterior surface.

9. The spacer of claim 7 wherein said bone ingrowth material is a composite including a rigid foam carbonaceous material and a thin film of metallic material deposited onto said carbonaceous material.

10. The spacer of claim 9 wherein said metallic material includes a group VB transition metal.

11. The spacer of claim 10 wherein said transition metal is tantalum, niobium or alloys thereof.

12. The spacer of claim 7 having a compressive endurance to 5 million cycles of at least about 100 lbs and a compressive strength of at least about 350 lbs.

13. The spacer of claim 12 having a compressive endurance to 5 million cycles of about 500 lbs and a compressive strength of about 1400 lbs.

14. The spacer of claim 7 wherein said bone ingrowth material defines at least about 10 pores per inch.

15. The spacer of claim 14 wherein said bone ingrowth material defines at least about 60 pores per inch.

16. The spacer of claim 15 wherein said bone ingrowth material defines about 80 pores per inch.

17. The spacer of claim 7 wherein said bone ingrowth material has a relative density of less than about 30%.

18. The spacer of claim 17 wherein said bone ingrowth material has a relative density of between about 16% to about 25%.

19. The spacer of claim 7 wherein said bone ingrowth material has a surface roughness of at least about 1 micron root mean square.

20. The spacer of claim 19 wherein said bone ingrowth material has a surface roughness of at least about 2 microns root mean square.

21. The spacer of claim 20 wherein said bone ingrowth material has a surface roughness of about 10 microns root mean square.

22. The spacer of claim 7 wherein said bone ingrowth material has a mean pore size of between about 200 microns to about 700 microns.

23. The spacer of claim 22 wherein said bone ingrowth material has a mean pore size of about 400 microns.

24. The spacer of claim 7, further comprising an osteogenic material contained within said chamber.

25. The spacer of claim 24 wherein said osteogenic material is autograft.

26. The spacer of claim 24 wherein said osteogenic material is a bioceramic.

27. The spacer of claim 26 wherein said bioceramic is a biphasic calcium phosphate ceramic.

28. The spacer of claim 24 wherein said osteogenic material is a therapeutically effective amount of a bone morphogenic protein in a pharmaceutically acceptable carrier.

29. The spacer of claim 24 wherein said osteogenic material is allograft.

30. A spinal prosthesis for engagement between vertebrae, comprising:

a solid D-shaped spacer body composed of a biocompatible bone ingrowth material having interconnected, continuous pores, the body including

a convexly curved anterior face;

a flat posterior face spaced apart from and opposing said anterior face;

two spaced apart, opposing lateral faces;

a superior face defining a first vertebral engaging surface; and

an inferior face spaced apart from and opposing said superior face, said inferior face defining a second vertebral engaging surface.

31. The prosthesis of claim 30 wherein said biocompatible bone ingrowth material is a composite including a nonmetallic rigid foam substrate formed by an interconnected network of carbonaceous material defining continuous, interconnected pores and a thin film of metallic material substantially covering said interconnected network.

32. The prosthesis of claim 31 wherein said metallic material includes a group VB transition metal.

33. The prosthesis of claim 32 wherein said transition metal is tantalum, niobium or alloys thereof.

34. The prosthesis of claim 31 wherein said composite at said vertebral engaging surfaces has a surface roughness of at least 1 micron root mean square.

35. The spacer of claim 34 wherein said composite at said vertebral engaging surfaces has a surface roughness of at least 2 micron root mean square.

36. The prosthesis of claim 30, further comprising an osteogenic material within the pores of said bone ingrowth material.

37. The prosthesis of claim 36 wherein said osteogenic material includes a bone morphogenic protein in a liquid carrier.

38. A spacer for engagement between vertebrae, comprising:

a body composed of a biocompatible bone ingrowth material having interconnected, continuous pores, said body including an anterior face and an opposite posterior face,

and a superior face and an inferior face defined between said anterior and posterior face, said superior and inferior faces defining vertebral engaging surfaces; and

an osteogenic material contained within said pores.

39. The spacer of claim 38 wherein said biocompatible bone ingrowth material is a composite including a nonmetallic rigid foam substrate formed by an interconnected network of carbonaceous material defining continuous, interconnected pores and a thin film of metallic material substantially covering said interconnected network.

40. The spacer of claim 39 wherein said metallic material includes a group VB transition metal.

41. The spacer of claim 40 wherein said transition metal is tantalum, niobium or alloys thereof.

42. The spacer of claim 39 wherein said composite at said vertebral engaging surfaces has a surface roughness of at least 1 micron root mean square.

43. The spacer of claim 42 wherein said composite at said vertebral engaging surfaces has a surface roughness of at least 2 micron root mean square.

44. The spacer of claim 38, wherein said osteogenic material includes a bone morphogenic protein in a liquid carrier.

45. The spacer of claim 28, wherein said carrier is a collagen sponge.

46. The spacer of claim 45 wherein said carrier is a biphasic hydroxyapatite/tricalcium phosphate ceramic.

47. The spacer of claim 24 further comprising an osteoinductive material contained within said pores.

48. The spacer of claim 47 wherein said material is a therapeutically effective amount of a bone morphogenic protein is a pharmaceutically acceptable liquid carrier.

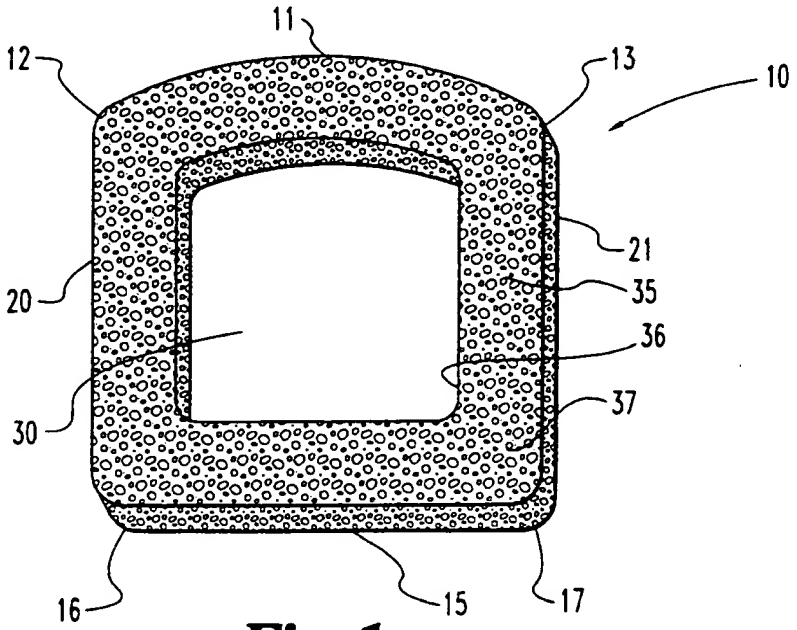

Fig. 1

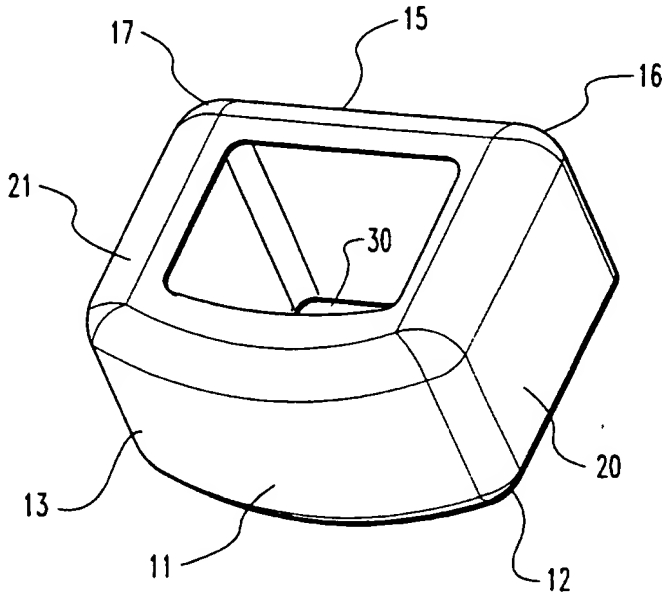

Fig. 2

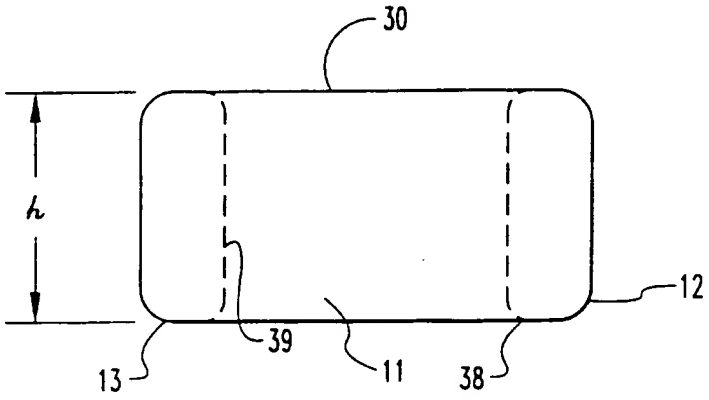

Fig. 3

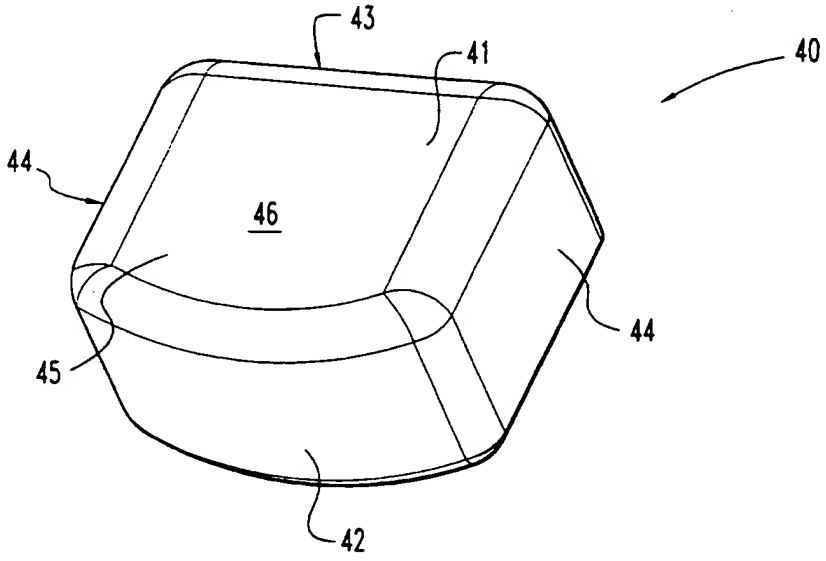

Fig. 4

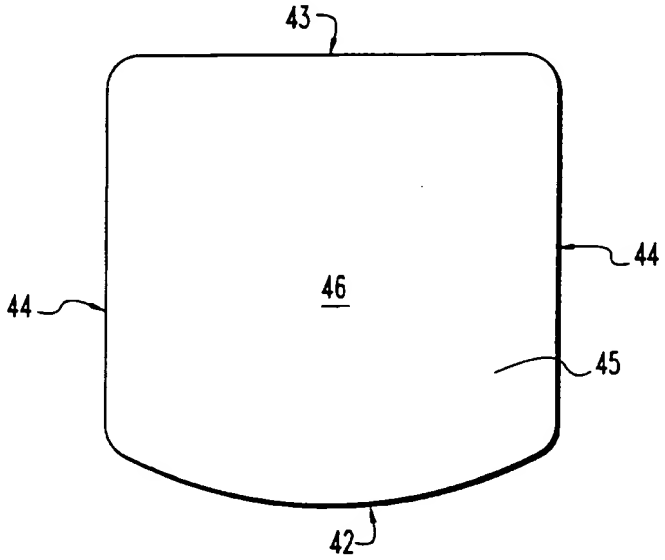

Fig. 5

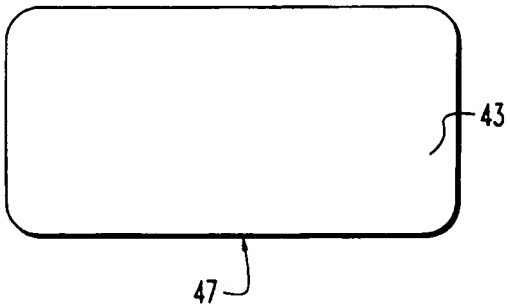

Fig. 6

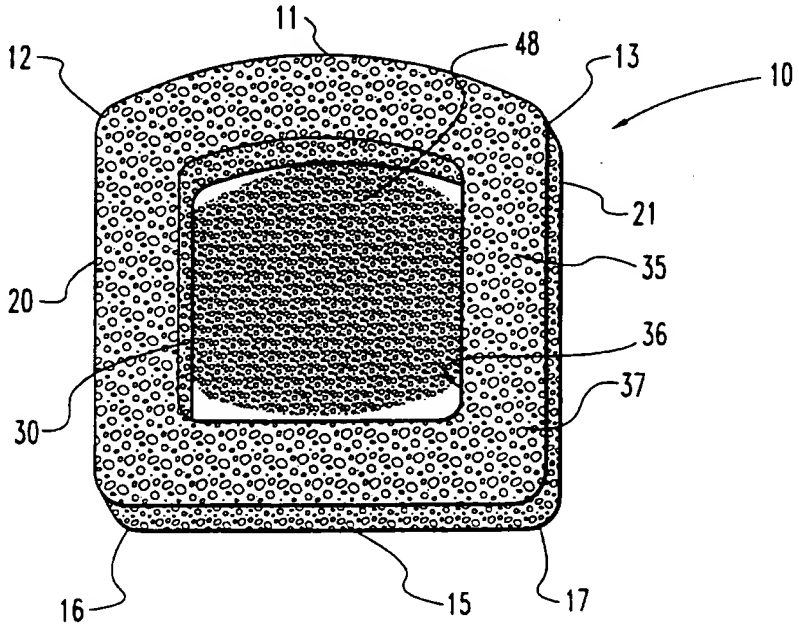

Fig. 7

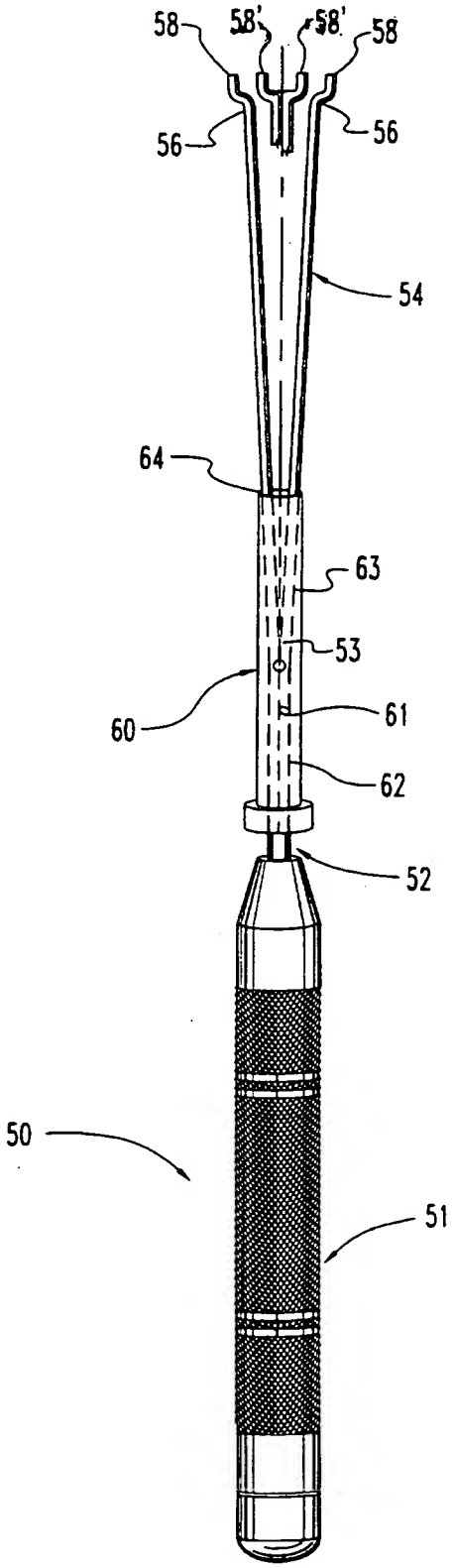

Fig. 8

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 96/16073

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 08306 A (SYNTHES AG) 30 March 1995	1,4,5, 30-33
A	see page 8, line 22 - page 10, line 3; figures 3,4	7,38
Y	US 5 282 861 A (KAPLAN) 1 February 1994 cited in the application see the whole document	1,4,5, 30-33

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 February 1997	12.02.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Smith, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inv onal Application No
PCT/US 96/16073

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9508306	30-03-95	BE-A-	1007549	01-08-95
		CA-A-	2151481	30-03-95
		EP-A-	0670702	13-09-95
		JP-T-	8503876	30-04-96
US-A-5282861	01-02-94	EP-A-	0560279	15-09-93
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